K063799

510(k) Summary of Safety and Effectiveness

JAN - 5 2007

Submitter:

- SPSmedical Supply Corp.
  6789 West Henrietta Road
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  Phone: (585)-359-0130
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- Establishment FDA Registration No.: 1319130
- Date Summary was prepared October 12th, 2006
- Gary J. Socola
  Printed name of person submitting for 510(k)
- Gary J. Socola
  Signature of person submitting for 510(k)
- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical STEAM*Plus*™ Steam Integrator
Classification Name:	Physical/Chemical Sterilization Process Indicator
Common Name:	Steam Integrator
Device Classification:	General Hospital - Class II, Regulation Number 880.2800
Product Code:	80JOJ
Predicate Device:	3M Thermalog steam sterilization integrator (510(k) No. K813202)

Device Description

The SPSmedical STEAM*Plus*™ Steam Integrator is designed to monitor sterilization parameters in steam sterilizers. It is a wicking style integrator which provides a visual indication that proper sterilization parameters were present within the sterilizers' chamber. Once the defined sterilization parameters have been reached the integrators pellet will melt and its dye will migrate from the non safe zone into the integrators safe zone. This will indicate to the user that the defined parameters for the integrator have been met.

Intended Use

The SPSmedical STEAM*Plus*™ Steam Integrator monitors sterilization parameters in both prevacuum and gravity type steam sterilizers. They are a reliable tool used for the monitoring of steam sterilization processes and provide a visual indication that proper sterilization parameters were present within the sterilizers' chamber. Integrators can be used in wrapped packs, trays, pouches, containers and in unwrapped trays.

Performance Testing

Testing was performed in accordance with AAMI/ANSI ST60:1996 - Sterilization of health care products - Chemical indicators - Part 1: General requirements.

Recommended Storage Conditions

Store in a cool, dry place (15-30°C).

Shelf life

The shelf life shall be 5 years from the date of manufacture, when stored in a cool, dry place (15-30°C).

Biocompatibility

Risk analysis concludes that the manufacturing and subsequent use of this product has a low associated risk and that the product is safe for its intended use and handling.

Conclusion

Data has demonstrated that the SPSmedical STEAM*Plus*™ Steam Integrator is equivalent to the predicate device. Results of testing show the SPSmedical STEAM*Plus* Integrator is a highly reliable and reproducible chemical integrator for steam sterilization processes and meets the performance claims for a class 5 integrator according to AAMI/ANSI ST60. It is capable of integrating time and temperature into an easy to interpret "Safe Zone" where the pellet only melts and advances into the safe zone when conditions needed for spore death have been reached.

The STEAM*Plus*™ Steam Integrator raises no issues related to safety or effectiveness and therefore should be allowed for market in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 5 2007

SPSmedical Supply Corporation
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K063799
Trade/Device Name: STEAMPlus™ Steam Sterilization Integrator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: December 21, 2006
Received: December 22, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

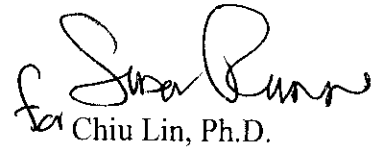
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K063799

Device Name: STEAM*Plus*™ Steam Sterilization Integrator

Indications For Use:

STEAM*Plus*™ Steam Sterilization Integrators are intended to be used to monitor parameters in steam sterilization cycles in healthcare facilities. The critical parameters for which the integrators will respond are time and temperature (under the presence of saturated steam). The integrators are intended to be used in steam cycles operating at 121°C - 134°C.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila F. Murphey MD

Anesthesiology, General Hosp...
Control, Dental Devices

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